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PATENT  
Attorney Reference Number 4239-67028-08

10/533811

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

**In re application of:** Valenzuela *et al.*

**Application No.** 10/533,811

**Filed:** April 29, 2005

**Confirmation No.** 7353

**For:** LUTZOMYIA LONGIPALPIS  
POLYPEPTIDES AND METHODS OF  
USE

**Examiner:** Not yet assigned

**Art Unit:** Unknown

**Attorney Reference No.** 4239-67028-08

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Agent  
for Applicant(s)

Date Mailed June 29, 2005

**TRANSMITTAL LETTER**

Enclosed for filing in the application referenced above are the following:

- Information Disclosure Statement
- Form 1449 and copies of references cited thereon (61)
- The Director is hereby authorized to charge any additional fees that may be required, or credit over-payment, to Deposit Account No. 02-4550. A copy of this sheet is enclosed.
- Please return the enclosed postcard to confirm that the items listed above have been received.

Respectfully submitted,

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cc: Docketing



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**INFORMATION DISCLOSURE STATEMENT PURSUANT TO 37 C.F.R. § 1.97(b)(2)**

Listed on the accompanying form PTO-1449 and enclosed herewith are several English-language documents. Applicants respectfully request that these documents be listed as references cited on the issued patent.

Applicants filed this Information Disclosure Statement ("IDS") within three months of the date of entry of the national stage as set forth in § 1.491 in an international application. As a result, no fee should be required to file this IDS. However, if the Patent Office determines that a fee is required for Applicants to file this IDS, authorization to charge any such fees to Deposit Account No. 02-4550 is provided on the accompanying transmittal letter.

The filing of this IDS shall not be construed to be an admission that the information cited in the statement is, or is considered to be, prior art or otherwise material to patentability as defined in 37 C.F.R. § 1.56.

Respectfully submitted,

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First Named Inventor	Valenzuela
Art Unit	Not yet assigned
Examiner Name	Not yet assigned

FOREIGN PATENT DOCUMENTS

Examiner's Initials*	Cite No. (optional)	Country	Number	Publication Date	Name of Applicant or Patentee
		WIPO/PCT	WO 95/06729	9 March 1995	Matlashewski <i>et al.</i>
		WIPO/PCT	WO 02/102324	27 Dec 2002	Valenzuela <i>et al.</i>
		WIPO/PCT	WO 2004/027041	1 April 2004	Valenzuela <i>et al.</i>

OTHER DOCUMENTS

	ADLER <i>et al.</i> , "The mouthparts, alimentary tract and salivary apparatus of the female <i>Phlebotomus papatasi</i> ," <i>Ann. Trop. Med. Parasitol.</i> 20:109, 1926.
	BARRAL <i>et al.</i> , "Human immune response to sand fly salivary gland antigens: a useful epidemiological marker?" <i>Am. J. Trop. Med. Hyg.</i> 62:740-745, 2000.
	BELKAID <i>et al.</i> , "A natural model of <i>Leishmania major</i> infection reveals a prolonged "silent" phase of parasite amplification in the skin before the onset of lesion formation and immunity," <i>J. Immunol.</i> 165:969-977, 2000.
	BELKAID <i>et al.</i> , "Delayed-type hypersensitivity to <i>Phlebotomus papatasi</i> sand fly bite: an adaptive response induced by the fly?" <i>Proc. Natl. Acad. Sci. USA</i> 97:6704-6709, 2000.
	BELKAID <i>et al.</i> , "Development of a natural model of cutaneous leishmaniasis: powerful effects of vector saliva and saliva preexposure on the long-term outcome of <i>Leishmania major</i> infection in the mouse ear dermis," <i>J. Exp. Med.</i> 188:1941-1953, 1998.
	CHARLAB <i>et al.</i> , "Toward an understanding of the biochemical and pharmacological complexity of the saliva of a hematophagous sand fly <i>Lutzomyia longipalpis</i> ," <i>Proc. Natl. Acad. Sci., USA.</i> 96(26):15155-15160, 1999
	HASKÓ <i>et al.</i> , "Adenosine receptor agonists differentially regulate IL-10, TNF-alpha, and nitric oxide production in RAW 264.7 macrophages and in endotoxemic mice," <i>J. Immunol.</i> , 157(10):4634-4640, 1996
	HASKÓ <i>et al.</i> , "Adenosine inhibits IL-12 and TNF-[alpha] production via adenosine A2a receptor-dependent and independent mechanisms," <i>FASEB J.</i> , 14(13):2065-2074, 2000
	GURUNATHAN <i>et al.</i> , "Vaccination with DNA encoding the immunodominant LACK parasite antigen confers protective immunity to mice infected with <i>Leishmania major</i> ," <i>J. Exp. Med.</i> 186:1137-1147, 1997.

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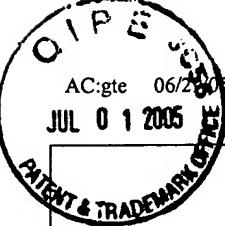
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		GURUNATHAN <i>et al.</i> , "Vaccine requirements for sustained cellular immunity to an intracellular parasitic infection," <i>Nat. Med.</i> 4:1409-1415, 1998.
		KAMHAWI <i>et al.</i> , "Protection against cutaneous leishmaniasis resulting from bites of uninfected sand flies," <i>Science</i> 290:1351-1354, 2000.
		KATZ <i>et al.</i> , "Adenosine, AMP, and protein phosphatase activity in sand fly saliva," <i>Am. J. Trop. Med. Hyg.</i> 62:145-150, 2000.
		KILLICK-KENDRICK, Biology of <i>Leishmania</i> in phlebotomine sand flies. In Biology of the Kinetoplastida. W. Lumsden and D. Evans, editors. Academic Press, New York. 395, 1979
		LERNER <i>et al.</i> , "Isolation of maxadilan, a potent vasodilatory peptide from the salivary glands of the sand fly <i>Lutzomyia longipalpis</i> ," <i>J. Biol. Chem.</i> , 266(17):11234-11236, 1991
		MAKOUL <i>et al.</i> , "Prostaglandin E2 inhibits the activation of cloned T cell hybridomas," <i>J. Immunol.</i> , 134(4):2645-2650, 1985
		MELLANBY, "Man's Reaction to Mosquito Bites," <i>Nature</i> 158(4016):554-555, 1946
		MÉNDEZ <i>et al.</i> , "The potency and durability of DNA- and protein-based vaccines against <i>Leishmania major</i> evaluated using low dose, intradermal challenge," <i>J. Immunol.</i> 166(8):5122-5128, 2001.
		MODI <i>et al.</i> , "A simple technique for mass rearing <i>Lutzomyia longipalpis</i> and <i>Phlebotomus papatasi</i> (Diptera: Psychodidae) in the laboratory," <i>J. Med. Ent.</i> 20:568-569, 1983.
		NONG <i>et al.</i> , "Peptides encoded by the calcitonin gene inhibit macrophage function," <i>J. Immunol.</i> , 143(1):45-49, 1989
		QURESHI <i>et al.</i> , "Immunomodulatory properties of maxadilan, the vasodilator peptide from sand fly salivary gland extracts," <i>Am. J. Trop. Med. Hyg.</i> , 54(6):665-671, 1996
		RIBEIRO <i>et al.</i> , "Blood-finding strategy of a capillary-feeding sandfly, <i>Lutzomyia longipalpis</i> ," <i>Comp. Biochem. Physiol.</i> , 83(4):683-686, 1986
		RIBEIRO <i>et al.</i> , "Salivary apyrase activity of some Old World phlebotomine sand flies," <i>Insect Biochem.</i> 19:409-412, 1989.
		RIBEIRO <i>et al.</i> , "Salivary glands of the sand fly <i>Phlebotomus papatasi</i> contain pharmacologically active amounts of adenosine and 5'-AMP," <i>J. Exp. Biol.</i> , 202(Pt. 11):1551-1559, 1999

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		SANTOLI <i>et al.</i> , "Prostaglandin E precursor fatty acids inhibit human IL-2 production by a prostaglandin E-independent mechanism," and Zurier, <i>J. Immunol.</i> , 143(4):1303-1309, 1989
		SJÖLANDER <i>et al.</i> , "Induction of a Th1 immune response and simultaneous lack of activation of a Th2 response are required for generation of immunity to leishmaniasis," <i>J. Immunol.</i> 160:3949-3957, 1998.
		SMELT <i>et al.</i> , "B cell-deficient mice are highly resistant to <i>Leishmania donovani</i> infection, but develop neutrophil-mediated tissue pathology," <i>J. Immunol.</i> 164:3681-3688, 2000.
		SOARES <i>et al.</i> , "The vasoactive peptide maxadilan from sand fly saliva inhibits TNF-alpha and induces IL-6 by mouse macrophages through interaction with the pituitary adenylate cyclase-activating polypeptide (PACAP) receptor," <i>J. Immunol.</i> 160:1811-1816, 1998
		STOCKMAN <i>et al.</i> , "The effect of prostaglandins on the in vitro blastogenic response of human peripheral blood lymphocytes," <i>Exp. Hematol.</i> , 2(2):65-72, 1974
		THEODOS <i>et al.</i> , "Analysis of enhancing effect of sand fly saliva on <i>Leishmania</i> infection in mice," <i>Infect. Immun.</i> 59:1592-1598, 1991.
		TITUS <i>et al.</i> , "Salivary gland lysates from the sand fly <i>Lutzomyia longipalpis</i> enhanced <i>Leishmania</i> infectivity," <i>Science</i> 239:1306-1308, 1988.
		TITUS <i>et al.</i> , "The role of vector saliva in transmission of arthropod-borne disease," <i>Parasitology Today</i> 6(5):157-160, 1990.
		VALENZUELA <i>et al.</i> , "The salivary apyrase of the blood-sucking sand fly <i>Phlebotomus papatasi</i> belongs to the novel <i>Cimex</i> family of apyrases," <i>J. Experimental Biology</i> , 204:229-237, 2001.
		VALENZUELA <i>et al.</i> , "Toward a defined anti- <i>Leishmania</i> vaccine targeting vector antigens: characterization of a protective salivary protein," <i>J. Exp. Med.</i> 194(3):331-342, 2001
		WEBSTER, "Role of purines in lymphocyte function," <i>Asian Pac. J. Allergy Immunol.</i> , 2(2):311-317, 1984
		XU <i>et al.</i> , "Protection against leishmaniasis by injection of DNA encoding a major surface glycoprotein, gp63, of <i>L. major</i> ," <i>Immunology</i> 84:173-176, 1995.

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		Database A_Genseq_29June04 Accession No. ABB71995, 26 March 2002, 1 page
		Database A_Genseq_29June04 Accession No. ABG18028, 18 Feb 2002, 1 page
		Database SPTREMBL Accession No. Q95WD8, 19 Dec 2001, 6 pages
		Database SPTREMBL Accession No. Q23404, 6 June 1998, 5 pages
		Database A_Genseq_29June04 Accession No. AAG03191, 6 Oct 2000, 1 page
		Database A_Genseq_29June04 Accession No. ABG24332, 18 Feb 2002, 1 page
		Database SPTREMBL Accession No. Q9HNC7 16 March 2001, 4 pages
		Database A_Genseq_29June04 Accession No. AAU48010, 27 Feb 2002, 1 page
		Database SPTREMBL Accession No. Q95WE2, 1 Dec 2001, 1 page
		Database PIR_78 Accession No. G81431, 31 March 2000, 2 pages
		Database SPTREMBL Accession No. Q9XZ44, 12 Nov 1999, 4 pages
		Database A_Genseq_29June04 Accession No. AAB94843 26 June 2001, 1 page
		Database A_Genseq_29June04 Accession No. ABB61398, 26 March 2002, 1 page
		Database A_Genseq_29June04 Accession No. AAB42952, 08 Feb 2001, 1 page
		Database SPTREMBL Accession No. Q9RVD4, 1 May 2000, 1 page
		Database SPTREMBL Accession No. Q95V88, 1 Dec 2001, 2 pages
		Database PIR_78 Accession No. B64020, 10 Sep 1999, 1 page
		Database A_Genseq_29June04 Accession No. ABB57882, 26 March 2002, 1 page

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		Database PIR_78 Accession No. T50116, 9 June 2000, 1 page
		Database PIR_78 Accession No. F90270, 24 May 2001, 1 page
		Database A_Genseq_29June04 Accession No. ABB58845, 26 March 2002, 1 page
		Database A_Genseq_29June04 Accession No. AAB83185, 9 July 2001, 1 page
		Database Swissprot_42 Accession No. Q57124, 10 Nov 1997, 1 page

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